

Vista Medical Technologies
Westborough, MA

510(k) Notification
3Dimensional Video Endoscope
January 1997

K970214

APR 14 1997 510(K) SUMMARY
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COMPANY NAME AND ADDRESS

Vista Medical Technologies
134 Flanders Road
Westborough, MA. 01581

CONTACT PERSON

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DEVICE TRADE NAME

3D Video Endoscope

COMMON NAME

Video Endoscope System

PREDICATE DEVICE

1. Device Name: 3D Scope Three Dimensional Medical VideoSystem
Classification: Camera, Television, Endoscopic, without audio
Manufacturer: American Surgical Technologies
300 Billerica Rd
Chelmsford, MA 01824
510(k) #: K923160 and K961182
2. Device Name: Oktas Video Endoscope System with Zoom
Classification: Endoscopes and Accessories -
21 CFR 876.1500
Manufacturer: Oktas
134 Flanders Rd
Westborough, MA 01581
510(k) #: K946171

3. Device Name: Zeiss EndoLive™ Stereo Endoscope
 Classification: Endoscopes and Accessories -
 21 CFR 876.1500
 Manufacturer: Carl Zeiss, Inc.
 Thornwood, NY 10594
 510(k) #: K950988

DEVICE DESCRIPTION

The 3D Video Endoscope System is a device used to allow observation in body cavities, organs, or canals through manmade or natural orifices. It is designed for use in all types of endoscopic and endoscopic assisted procedures, including general thoracic and as an aid in visualization of the evacuated cardiac chamber. The product is an integrated endoscope and video camera. The system will be supplied as a 3D Video Endoscope and Camera Control Unit. The device is designed to work with commercially available light sources, and video monitors or head mounted displays (HMD). Additionally the device can be mounted in a rack and used as one module of a rack mounted system.

INTENDED USE

The device is intended for use in all types of endoscopic and endoscopic assisted procedures, including general thoracic and as an aid in visualization of the evacuated cardiac chamber.

PERFORMANCE DATA

IEC 601-1	"General Safety Requirements for Medical Electrical Equipment"
IEC 601-1-2	"Electrical Magnetic Compatibility"
IEC 601-2-18	"Safety of Endoscopic Equipment"
ISO 10993	"Biological Evaluation of Medical Devices"
UL 544	"Standard for Safety Medical and Dental Equipment"
Optical Test Data	